REMARKS

Applicants hereby request further consideration of the application in view of the amendments above and the comments that follow.

Applicants wish to thank the Examiner for the courtesies extended to Applicants' attorney, David Beatty, during the interview of April 2, 2008.

Status of the Claims

Claims 1-5, 7, 9, 11, 12, 14, 15, 17, 18 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,215,198 to Gordon in view of U.S. Patent No. 5,094,955 to Calandra et al. alone or, alternatively, further in view of U.S. Patent No. 4,829,005 to Friedman et al. Claims 11-13, 20 and 35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Calandra et al. alone or further in view of Friedman et al., taken further in view of U.S. Patent No. 4,643,197 to Greene.

The Rejections under Sections 102 and 103

New Claims 41-44:

New Claim 41 has been written as suggested by the Examiner during the telephonic interview and recites:

> 41. An integrated filtration and detection device for collecting and detecting the growth of microorganisms in a specimen, said device comprising:
>
> a) a container including a side wall and a fixed end wall defining a chamber therein and having an inlet and an outlet in fluid communication with said chamber, wherein said end wall defines a continuous closed surface that is continuous with said side wall and free of openings;
>
> b) a filter for filtering fluids, said filter mounted in said chamber between said inlet and said outlet; and
>
> c) a sensor mounted in said chamber parallel to and against said end wall of said chamber, said sensor operative to exhibit a change in

> a measurable property thereof upon exposure to changes in said chamber due to microbial growth;
>
> wherein said container has a transparent section and changes in said measurable property of said sensor are detectable through said transparent section; and said sensor and said filter are disposed at opposed ends of said chamber.

An integrated filtration and detection device as recited in Claim 41 may provide certain distinct advantages. The claimed construction may provide a chamber for the specimen and culturing medium that is hermetically sealed, the hermetic seal being sufficiently robust to withstand agitation (*e.g.*, shaking of the container) and high internal pressure (*e.g.*, from heating and/or microbial gas production) without breaching the hermetic seal. The claimed construction may permit the container of the device to be inverted to ensure effective and reliable liquid contact between the sensor and the culturing medium without jeopardizing the hermetic seal. The enablement of liquid contact between the culturing medium and the sensor and the ability to safely and reliably withstand agitation and heating may provide for particularly rapid and effective detection of microbial growth in a specimen. As such, integrated filtration and detection devices as recited in Claim 41 may be particularly well-suited for on-line or real-time sampling and testing for microbial growth.

By contrast, the removable and replaceable cap **15** (**Figures 1-5**) of Gordon is clearly not a fixed end wall of the container **11**. In the embodiment shown in **Figures 6** and **7** of Gordon, the top end wall has a connector port **45** formed therein. Applicants respectfully submit that it would not have been obvious to the ordinarily skilled artisan to eliminate the removable cap **15** or the connector port **45** from Gordon inasmuch as such modification would fundamentally alter the operation and functionality of the Gordon devices. In particular, a primary objective of Gordon is to provide a stackable unit. See, for example, Gordon at col. 2, lines 39-46, col. 3, lines 18-21 and col. 7, lines 39-55. A modification of the Gordon devices as needed to correspond to the claimed invention would presumably negate this objective. The remaining cited art do not satisfy the deficiencies of Gordon in this regard.

Accordingly, Claim 41 is patentably distinguishable from the cited art for at least these reasons. Claims 42-44 depend from Claim 41 and are therefore allowable as well for at least these reasons. Claim 42 further recites:

> 42. The device of Claim 41 wherein said container is unitary and said inlet and said outlet are the only openings into said container communicating with said chamber.

By contrast, in the embodiment shown in **Figures 1-5** of Gordon, the vessel includes ports **13**, **19** and **41**. In the embodiment shown in **Figures 6** and **7** of Gordon, the vessel includes ports **13**, **19** and **45**. Accordingly, Claim 42 is patentably distinguishable from the cited art for these additional reasons.

New Claims 45-47:

Former Claim 36 has been rewritten in independent form as new Claim 45, which now recites a "product" rather than a "device" as suggested by the Examiner. It is Applicants' understanding that recitation in this manner is sufficient to render the recited liquid culturing medium as an element of the claim entitled to patentable weight. More particularly, Claim 45 recites:

> 45. An integrated filtration and detection product for collecting and detecting the growth of microorganisms in a specimen, said product comprising:
>
> a container defining a chamber therein and having an inlet and an outlet in fluid communication with said chamber;
>
> a liquid culturing medium disposed in said chamber;
>
> a filter for filtering fluids, said filter mounted in said chamber between said inlet and said outlet; and
>
> a sensor mounted in said chamber parallel to and against an end wall of said chamber, said sensor operative to exhibit a change in a measurable property thereof upon exposure to changes in said chamber due to microbial growth;
>
> wherein said container has a transparent section and changes in said measurable property of said sensor are detectable through said transparent section; and said sensor and said filter are disposed at opposed ends of said chamber;

wherein said sensor resides at a lower end of said chamber and below said filter; and

wherein said liquid culturing medium is disposed in said lower end of said chamber and contacts said sensor in said lower end of said chamber.

For example, as illustrated in **Figures 6** and **7** of Applicants' specification, the device **100** has an operative testing orientation wherein the sensor **120** is located below the filter **130** and liquid culturing medium is disposed in the chamber. Such positioning may ensure that the culturing medium adequately contacts the sensor **120**, which may be a sensor of the type that requires fluid contact to properly react to and indicate the presence of microorganisms or their growth byproducts. Such placement may be particularly valuable when the device is agitated to promote microorganism growth as discussed above. The device of Gordon does not have an operative testing orientation wherein the cap **15** or the top wall having the connector port **45** resides at a lower end of the container and below the filter **23**. In view of the leakage risks discussed above and in Applicants' prior response, the ordinarily skilled artisan would have regarded inversion of the containers of Gordon to be impractical and unsafe.

New Claim 46 depends from Claim 45 and further recites:

46. The device of Claim 45 wherein:
said container includes a side wall defining the chamber;
said end wall is fixed and defines a continuous closed surface that is continuous with the side wall and free of openings; and
said inlet and said outlet are each located above said sensor.

Claim 46 thus more particularly sets forth the structure of the container, its side wall and its end wall as well as the structural relationships between the sensor and the inlet and outlet. Accordingly, Claim 46 is also patentably distinguishable from the cited art for the reasons discussed above with regard to Claim 41.

New Claim 47 depends from Claim 45 and further recites:

47. The device of Claim 45 wherein said chamber is fully sealed.

Accordingly, Claim 47 is also patentably distinguishable from the cited art for the reasons discussed above with regard to Claim 42.

Claims 1-5, 7, 9, 11-15, 17, 18, 20, 21, 29, 33-35, 39 and 40:

Regarding the rejections of Claims 1-5, 7, 9, 11-15, 17, 18, 20, 21, 29, 33-35, 39 and 40, Applicants hereby incorporate Applicants' arguments from the Response dated October 24, 2007 and respectfully submit that the claimed invention would not have been obvious to one of ordinary skill in the art even in view of Freidman. While in the same general field of endeavor, Friedman is directed to a very different device and method of use than Gordon. As such, the ordinarily skilled artisan would not have turned to Freidman for possible modifications to Gordon. It is not apparent from either Friedman or Gordon how the seal as discussed in Friedman would have been relevant to the procedure of Gordon. Accordingly, Claims 1-5, 7, 9, 11-15, 17, 18, 20, 21, 29, 33-35, 39 and 40 are patentable over the art now cited.

CONCLUSION

Applicants respectfully submit that this application is now in condition for allowance, which action is requested. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on April 7, 2008.

Kirsten S. Carlos